

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Morishita et al.

Application No. 09/869,475

Filed: October 10, 2001

Confirmation No. 4309

For: GENE THERAPY FOR DIABETIC
ISCHEMIC DISEASE

Examiner: Brian A. Whiteman

Art Unit: 1635

Attorney Reference No. 6235-59221-01

DECLARATION UNDER § 1.132

1. I, Dr. Ryuichi Morishita, am a co-inventor named in the above-referenced patent application.

2. I have read and understand the above-referenced patent application, including the pending claims, and the Office action dated May 10, 2006.

3. It is my understanding that in the Office action of May 10, 2006, claims 9, 11, 12, 14, 23-26, and 51-52 are rejected under 35 U.S.C. § 103(a) as unpatentable over Isner *et al.* (WO 98/19712), an article from the Japan Financial Times (December 14, 1998), and Li *et al.* (U.S. Patent No. 6,066,123) in further view of Morishita *et al.* (EP 0847757). However, it was not obvious to me and my co-inventor Dr. Toshio Ogihara that diabetic ischemic disease could be treated by administration of hepatocyte growth factor (HGF) gene every few weeks or every few days.

4. At the time the invention was made, it was understood by those skilled in the art such as myself that HGF had a short half-life, such as about 10 minutes. Therefore, it was not expected that the effects of HGF expression would be sustained for a few days or even a few weeks if only administered once over this time period.